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276 \ 35 MALIGNIN ANTIBODY RETURNS TO NORMAL ON SUCCESSFUL TREATMENT OF BREAST CANCER. S. Bogoch, M.D., Ph.D., E. Bogoch, M.D.

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Anti-malignin antibody in serum (AMAS) is an IgM produced by the patient against a defined 10KD oncoprotein located in cytoplasmic and outer cancer cell membranes (Cancer Detec Prev 1988;12:312-20). AMAS has been shown to be elevated in early malignancy (Lancet 1991;337:977), is cytotoxic to cancer cells in vitro, and its concentration relates quantitatively in vivo to survival of cancer patients. AMAS determinations were performed blind in 176 patients with breast disorders, benign and malignant, and in 174 normal healthy and medical non-cancer disorder patients. AMAS was elevated ( $\geq 135$  ug/ml) in early breast cancer regardless of whether first occurrence (N=65) or recurrence (N=16), and whether localized (N=73) or metastasized (N=8). Successful treatment resulting in 'no clinical evidence of cancer', whether achieved by surgery, chemotherapy, radiation, other, or a combination thereof, was associated with normal AMAS values ( $< 135$  ug/ml) in 83% within one year, and in 96% one to 27 years after successful treatment. In longitudinal studies of individual patients, AMAS changed from elevated to normal in five weeks to eight months (mean 3 months). AMAS therefore appears to be a 'transformation antibody', that is, elevated in response to the appearance of cells in the body transformed to the malignant state, then returns to normal when the cancer is no longer evident. AMAS is therefore used for detection and monitoring.

377 \ 45 MALIGNIN ANTIBODY AS EARLY WARNING. E. Bogoch, M.D., S. Bogoch, M.D., Ph.D.

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Clinical signs and symptoms of cancer frequently occur only relatively late in the disease. Similarly, tests based upon the measurement of antigen (eg. CEA, CA125, CA15.3, CA19.9, PSA) depend upon a critical tumor mass releasing sufficient antigen into the blood to be detected. On the other hand, the measurement of antibody might be an earlier indication. Anti-malignin antibody in serum (AMAS) is an IgM produced by the patient against a defined 10KD oncoprotein, malignin, located in cytoplasmic and outer cancer cell membranes (Cancer Detec Prev 1988;12:312-20). 3,498 AMAS determinations in non-terminal cancer patients and controls found elevated values ( $\geq 135$  ug/ml) in 95% with an apparent false positive of 5% on first determination, and less than 1% on repeat determination (Lancet 1991;337:977). In a separate study of breast cancer by Thornthwaite et al. (unpublished), 5 out of 170 healthy control individuals (2.9%) had elevated values ('false positives'). Subsequently, within two weeks to three years, 4 out of these 5 developed clinical cancer: cervical carcinoma, basal cell carcinoma of chest wall, squamous cell carcinoma of tongue, and carcinoma of tonsil. The fifth had ulcerative colitis. Four are in their 30's, one is age 64. From a practical point of view, it would appear that purported healthy individuals who have elevated AMAS values in the absence of signs and symptoms of cancer should be followed.

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